

PATENT
454313-2335.1

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 12, 13, 15-24, 28-51 and 54-66 are pending in this application. Claims 12, 13, 20, 24, 40, 41, 47 and 51 have been amended, and claims 25, 26, 51, 52, 67 and 68 have been cancelled. Support for the amended claims is found throughout the specification and in the claims as originally filed.

No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claims 67 and 68 were objected to under 37 C.F.R. 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 67 and 68 have been cancelled, rendering the objection moot.

Claim 40 and 41 were objected to because the claims were allegedly grammatically incorrect, redundant and confusing. It is believed that the amendments to claims 40 and 41 overcome the objection.

Consequently, reconsideration and withdrawal of the objections to the claims are requested.

III. THE REJECTION UNDER 35 U.S.C. §112, 2ND PARAGRAPH, IS OVERCOME

Claims 40-64, 67 and 68 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

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The Examiner objected to the recitation of "enhancing the immunogenicity of a polypeptide" in the preamble of claims 40 and 41. As suggested by the Examiner, claims 40 and 41 have been amended such that they are now directed to "enhancing the host immune response" to a polypeptide. Support for this recitation may be found throughout the specification and specifically in the Abstract.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 12, 15-26, 28-35, 37, 39, 40, and 42-68 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet *et al.* (U.S. 6,217,883) in view of Nabel *et al.* (US 5,910,488). Claims 13, 18-26, 37, 39, 41, 45-53, 65 and 66 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet *et al.*, *supra*, as evidenced by Meehan *et al.* (J. Gen. Virol. 1998, 79:2171-79), in view of Mathiowitz *et al.* (U.S. 6,475,799). These rejections are traversed and will be addressed collectively.

The current claims are directed to immunogenic preparations comprising at least one plasmid encoding and expressing PCV-2 ORF1 or PCV-2 ORF2, plus a cationic lipid and/or a carbomer, and methods for enhancing a host immune response using the preparations. To the contrary, Poet *et al.* relates to DNA vaccines against beak and feather disease virus (BFDV) and PCV-1. Poet *et al.* does not teach or suggest a DNA vaccine comprised of a plasmid encoding and expressing PCV-2. One cannot extrapolate from the teachings of Poet *et al.* to the instant invention because a vaccine comprising DNA derived from BFDV or PCV-1 would not be effective against PCV-2. Therefore, the skilled artisan would not be able to arrive at the claimed invention, and no combination of references that relies on Poet *et al.* can properly be used to render the instant invention obvious.

It is respectfully submitted that the cited references, alone or in combination, do not teach or suggest the presently claimed invention. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are requested.

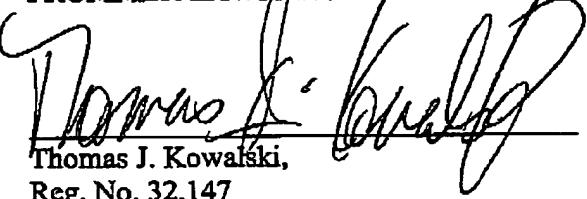
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CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By:

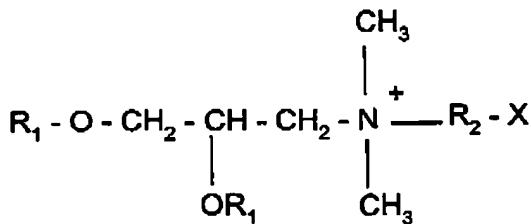

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

12. (Amended) An immunogenic preparation comprising a complex of: at least one plasmid encoding and expressing *in vivo* in a porcine host an isolated nucleic acid molecule selected from the group consisting of open reading frame (ORF) 1 of porcine circovirus type II (PCV-2)[.] and ORF2 of PCV-2[., ORF1 of porcine circovirus type I (PCV-1) and ORF2 of PCV-1]; and, an adjuvant which comprises a cationic lipid of formula



in which R₁ is a saturated or unsaturated linear aliphatic radical having from 12 to 18 carbon atoms, R₂ is aliphatic radical comprising from 2 to 3 carbon atoms, and X is an hydroxyl or amine group.

13. (Amended) An immunogenic preparation comprising at least one plasmid encoding and expressing *in vivo* in a porcine host an isolated nucleic acid molecule selected from the group consisting of open reading frame (ORF) 1 of porcine circovirus type II (PCV-2)[.] and ORF2 of PCV-2[., ORF1 of porcine circovirus type I (PCV-1) and ORF2 of PCV-1]; and, an adjuvant comprising a carbomer.

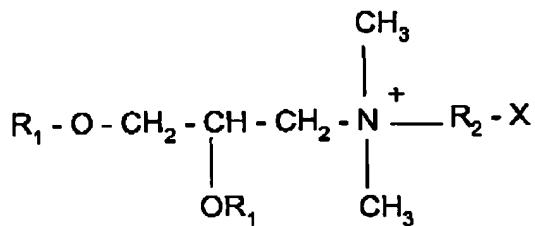
20. (Twice Amended) The immunogenic preparation according to claim 12 or 13, further comprising a plasmid encoding and expressing an immunogen from a porcine pathogenic agent other than PCV-2[or PCV-1].

24. (Twice Amended) The immunogenic preparation according to any one of claims 12, 13, 15, or 16, wherein the preparation includes at least [one] two plasmids, one that contains and expresses ORF1 of PCV-2, and one that contains and expresses ORF2 of PCV-2.

40. (Amended) A method for enhancing a host immune response, in a porcine host, to [the immunogenicity of] a polypeptide encoded by open reading frame (ORF) 1 of porcine circovirus type II (PCV-2)[.] or ORF2 of PCV-2, [ORF1 of porcine circovirus type I (PCV-1) or

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ORF2 of PCV-1 expressed *in vivo* in a porcine host by at least one plasmid that encodes and expresses *in vivo* in a porcine host the polypeptide,] said method comprising administering to the porcine host [the] at least one plasmid that encodes and expresses ORF1 of PCV-2 or ORF2 of PCV-2, wherein the plasmid is [as a] complexed with an adjuvant which comprises a cationic lipid of formula



in which R_1 is a saturated or unsaturated linear aliphatic radical having from 12 to 18 carbon atoms, R_2 is aliphatic radical comprising from 2 to 3 carbon atoms, and X is an hydroxyl or amine group.

41. (Amended) A method for enhancing a host immune response, in a porcine host, to [the immunogenicity of] a polypeptide encoded by open reading frame (ORF) 1 of porcine circovirus type II (PCV-2)[,] or ORF2 of PCV-2, [ORF1 of porcine circovirus type I (PCV-1) or ORF2 of PCV-1 expressed *in vivo* in a porcine host by at least one plasmid that encodes and expresses *in vivo* in a porcine host the polypeptide,] said method comprising administering to the porcine host [the] at least one plasmid that encodes and expresses ORF1 of PCV-2 or ORF2 of PCV-2, and [with] an adjuvant which comprises a carbomer.

47. (Amended) The method according to claim 40 or 41, wherein the administering includes administering a plasmid encoding and expressing an immunogen from a porcine pathogenic agent other than PCV-2 [or PCV-1].

51. (Amended) The method according to any one of claims 40 or 41, wherein the administering includes administering at least [one] two plasmids, one that contains and expresses ORF1 of PCV-2, and one that contains and expresses ORF2 of PCV-2.